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IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

Applicant: Shimp *et al.*
Serial No.: 10/681,651
Filed: October 8, 2003
For: COUPLING AGENTS FOR ORTHOPEDIC BIOMATERIALS

Examiner: Kennedy, S.E.
Art Unit: 1615

Mail Stop Amendment
Commissioner for Patents
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Typed or Printed Name of person signing certificate	

STATEMENT UNDER 37 C.F.R. §§ 1.56, 1.97, AND 1.98

Pursuant to the duty of disclosure under 37 C.F.R §§ 1.56, 1.97 and 1.98, Applicant requests consideration of this Information Disclosure Statement.

Type of Statement

The present Information Disclosure Statement is:

- ☐ An *original* Information Disclosure Statement; or
- ☒ A *supplemental* Information Disclosure Statement.

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Compliance with 37 CFR § 1.97

The present Information Disclosure Statement is being filed:

[X] Pursuant to 37 CFR § 1.97(c) after the dates listed above but before the mailing date of any of a final action under § 1.113, a notice of allowance under § 1.311, or an action that otherwise closes prosecution in the application; Applicant hereby certifies that *either*:

[] each item of information contained in the information disclosure statement was first cited in any communication from a foreign patent office in a counterpart foreign application not more than three months prior to the filing of the information disclosure statement; or

[] That no item of information contained in the information disclosure statement was cited in a communication from a foreign patent office in a counterpart foreign application, and, to the knowledge of the person signing the certification after making reasonable inquiry, no item of information contained in the information disclosure statement was known to any individual designated in § 1.56(c) more than three months prior to the filing of the information disclosure statement; or

[X] Includes herewith the fee set forth in § 1.17(p).

Content of the Information Disclosure Statement

Applicant hereby makes of record in the above-identified application the references listed on the attached form SB/08. The order of presentation of the references should not be construed as an indication of the importance of the references.

Applicant includes copies of references as indicated below:

- ☒ A copy of each of the references cited on the attached form SB/08 is enclosed, except for U.S. patents and published U.S. patent applications for which the submission requirement has been waived by the PTO in the Official Gazette Notice of August 5, 2003, for applications filed after June 30, 2003;
- ☐ Copies of references indicated with an asterisk on the attached form SB/08 are not included pursuant to 37 CFR § 1.98(d) because they were previously provided to the United States Patent Office in an Information Disclosure Statement that complies with 37 CFR § 1.98(a)-(c) and was submitted in the following patent application that is relied upon in the present case for an earlier effective filing date under 35 USC § 120:

Serial Number	Filing Date	Status

- ☐ Copies of English translations of one or more non-English references are included.

Applicant hereby makes the following additional information of record in the above-identified application:

Applicant certifies that the Information Disclosure Statement *either*:

- ☒ Does not contain non-English language citations;
- ☐ Includes one or more translations of a non-English citation; or
- ☐ Does contain non-English language citations, of which the following is a concise explanation:

Remarks

The submission of this Information Disclosure Statement should not be construed as a representation that a search has been made.

The submission of this Information Disclosure Statement shall not be construed to be an admission that the information cited in the statement is, or is considered to be, material to patentability as defined in § 1.56(b) .

The submission of this Information Disclosure Statement shall not be construed as a representation that the information cited in the Statement is, or is considered to be, in fact, prior art as defined by 35 USC § 102.

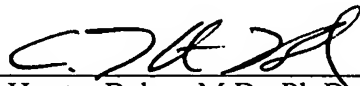
It is respectfully requested that:

1. The Examiner consider completely the cited information, along with any other information, in reaching a determination concerning the patentability of the present claims;
2. The enclosed form PTO-1449 be signed by the Examiner to evidence that the cited patent(s) and publication(s) has (have) been fully considered by the Patent and Trademark Office during the examination of this application; and
3. The citations for the patents and publications be printed on any patent which issues from this application.

Notwithstanding any statements by Applicants, the Examiner is urged to form his or her own conclusions regarding the relevance of the cited references.

Respectfully submitted,

Dated: February 12, 2007


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PTO/SB/08A (07-06)

Approved for use through 09/30/2006. OMB 0651-0031

U.S. Patent and Trademark Office: U.S. DEPARTMENT OF COMMERCE

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Substitute for form 1449/PTO INFORMATION DISCLOSURE STATEMENT BY APPLICANT <i>(Use as many sheets as necessary)</i>				Complete if Known	
				Application Number	10/681,651
				Filing Date	October 8, 2003
				First Named Inventor	Shimp <i>et al.</i>
				Art Unit	1615
Examiner Name	Kennedy, S.E.				
Attorney Docket Number	2004367-0029				
Sheet	1	Of	5		

U.S. PATENT DOCUMENTS					
Examiner Initials	Cite No. ¹	Document Number	Publication Date MM-DD-YYYY	Name of Patentee or Applicant of Cited Document	Pages, Columns, Lines, Where Relevant Passages or Relevant Figures Appear
		Number-Kind Code ² (if known)			
		US-4,187,852	February 12, 1980	Urry et al.	
		US-4,192,021	March 11, 1980	Deibig et al.	
		US-4,263,185	April 21, 1981	Belykh et al.	
		US-4,314,380	February 9, 1982	Miyata et al.	
		US-4,365,359	December 28, 1982	Raab	
		US-4,394,370	July 19, 1983	Jefferies	
		US-4,440,750	April 3, 1984	Glowacki et al.	
		US-4,516,276	May 14, 1985	Mittelmeier et al.	
		US-4,595,713	June 17, 1986	St. John	
		US-4,637,931	January 20, 1987	Schmitz	
		US-4,776,890	October 11, 1988	Chu	
		US-4,863,732	September 5, 1989	Nathan et al.	
		US-4,882,149	November 21, 1989	Spector	
		US-5,073,114	December 17, 1991	Detsch	
		US-5,338,772	August 16, 1994	Bauer et al.	
		US-5,417,975	March 23, 1995	Lussi et al.	
		US-5,507,813	April 16, 1996	Dowd et al.	
		US-5,531,791	July 2, 1996	Wolfenbarger, Jr.	
		US-5,552,454	September 3, 1996	Kretschmann, et al.	
		US-5,573,771	November 12, 1996	Geistlich et al.	
		US-5,607,269	March 4, 1997	Dowd et al.	
		US-5,624,463	April 29, 1997	Stone, et al.	
		US-5,837,752	November 17, 1998	Shastri, et al.	
		US-5,899,939	May 4, 1999	Boyce et al.	
		US-6,033,582	March 7, 2000	Lee et al.	
		US-6,119,028	September 12, 2000	Schulman et al.	
		US-6,183,498	February 6, 2001	Devore, et al.	
		US-6,201,039	March 13, 2001	Brown et al.	
		US-6,217,614	April 17, 2001	Fages et al.	
		US-6,261,586	July 17, 2001	McKay	
		US-6,294,187	September 25, 2001	Boyce, et al.	
		US-6,340,477	January 22, 2002	Anderson	
		US-6,376,573	April 23, 2002	White, et al.	
		US-6,395,036	May 28, 2002	Czernuszka et al.	
		US-6,441,073	August 27, 2002	Tanaka, et al.	
		US-6,696,073	February 24, 2004	Boyce, et al.	
		US-6,984,236	January 10, 2006	Raab	

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				Complete if Known	
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		US-6,933,328	August 23, 2005	Schact	
		US-2003/0039676	February 27, 2003	Boyce, et al.	
		US-2003/0045942	March 6, 2003	Lai, et al.	
		US-2003/0114552	June 19, 2003	Schacht	
		US-2003/0130736	July 10, 2003	Raab	
		US-2003/0180344	September 25, 2003	Wise, et al.	
		US-2003/0236573	December 25, 2003	Evans, et al.	
		US-2004/0024457	February 5, 2004	Boyce, et al.	
		US-2004/0034434	February 19, 2004	Evans, et al.	
		US-2004/0064193	April 1, 2004	Evans, et al.	
		US-2004/0138758	July 15, 2004	Evans, et al.	
		US-2004/0146543	July 29, 2004	Shimp, et al.	
		US-2005/0281856	December 22, 2005	McGlohorn, et al.	
		US-2005/0238683	October 27, 2005	Adhikari, et al.	

FOREIGN PATENT DOCUMENTS						
Examiner Initials	Cite No. ¹	Foreign Patent Document Country Code ³ -Number ⁴ -Kind Code ⁵ (if known)	Publication Date MM-DD-YYYY	Name of Patentee or Applicant of Cited Document	Pages, Columns, Lines, Where Relevant Passages Or Relevant Figures Appear	T ⁶
		EP- 0 413 482	March 12, 1997	Galileo Electro-Optics Corp.		
		WO-03/034937	May 1, 2003	Raab		
		WO-04/032988	April 22, 2004	Osteotech, Inc.		
Examiner Signature				Date Considered		

*EXAMINER: Initial if reference considered, whether or not citation is in conformance with MPEP 609. Draw line through citation if not in conformance and not considered. Include copy of this form with next communication to applicant. ¹Applicant's unique citation designation number (optional). ²See Kinds Codes of USPTO Patent Documents at www.uspto.gov or MPEP 901.04. ³Enter Office that issued the document, by the two-letter code (WIPO Standard ST.3). ⁴For Japanese patent documents, the indication of the year of the reign of the Emperor must precede the serial number of the patent document. ⁵Kind of document by the appropriate symbols as indicated on the document under WIPO Standard ST. 16 if possible. ⁶Applicant is to place a check mark here if English language Translation is attached.

This collection of information is required by 37 CFR 1.97 and 1.98. The information is required to obtain or retain a benefit by the public which is to file (and by the USPTO to process) an application. Confidentiality is governed by 35 U.S.C. 122 and 37 CFR 1.14. This collection is estimated to take 2 hours to complete, including gathering, preparing, and submitting the completed application form to the USPTO. Time will vary depending upon the individual case. Any comments on the amount of time you require to complete this form and/or suggestions for reducing this burden, should be sent to the Chief Information Officer, U.S. Patent and Trademark Office, P.O. Box 1450, Alexandria, VA 22313-1450. DO NOT SEND FEES OR COMPLETED FORMS TO THIS ADDRESS. SEND TO: Commissioner for Patents, P.O. Box 1450, Alexandria, VA 22313-1450.

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Examiner Name	Kennedy, S.E.				
Sheet	3	Of	5	Attorney Docket Number	2004367-0029

NON PATENT LITERATURE DOCUMENTS			
Examiner Initials	Cite No. ¹	Include the name of the author (in CAPITAL LETTERS), title of the article (when appropriate), title of the item (book, magazine, journal, serial, symposium, catalog, etc.), date, page(s), volume-issue number(s), publisher, city and/or country where published.	T ²
		Aspenberg et al., "Bone Morphogenetic Protein Induces Bone in the Squirrel Monkey, But Bone Matrix Does Not", Thirty Ninth Annual Meeting, Orthopaedic Research Society, 101, 1993.	
		Ballock et al., "Regulation of Collagen Expression in Periosteal Cells by Three Members of the TGF- β Superfamily", <i>Thirty Ninth Annual Meeting, Orthopaedic Research Society</i> , 734, 1993.	
		Bonar et al., "Structural and Composition Studies on the Mineral of Newly Formed Dental Enamel: A Chemical, X-Ray Diffraction, and P and Proton Nuclear Magnetic Resonance Study", <i>J. Bone Min. Res.</i> , 6(11): 1167-76, 1991.	
		Cook et al., "Recombinant Human Osteogenic Protein-1 (RHOP-1) Heals Segmental Long-Bone Defects in Non-Human Primates", Thirty Ninth Annual Meeting, Orthopaedic Research Society, 484, 1993.	
		Dandurand et al., "Study of the Mineral-Organic Linkage in an Apatitic-Reinforced Bone Cement", <i>J. Biomed. Mater. Res.</i> , 24: 1377-84, 1990.	
		Delpech et al., "Calcium Phosphate and Polymer Interfaces in Orthopaedic Cements", <i>Clin. Mater.</i> , 5: 209-16, 1990.	
		Dupraz et al., "Characterization of Silane-Treated Hydroxyapatite Powders for Use as Filler in Biodegradable Composites", <i>J. Biomed. Mater. Res.</i> , 30: 231-38, 1996.	
		Forssell et al., "Experimental Osteosynthesis with Liquid Ethyl Cyanacrylate Polymerized with Ultrasound", <i>Arch Orthop Trauma Surg</i> , 103: 278-83, 1984.	
		Hunt et al., "Healing of a Segmental Defect in the Rat Femur Using a Bone Inducing Agent (BIA) Derived from a Cultured Human Osteosarcoma Cell Line (SAOS-2)", Thirty Ninth Annual Meeting, Orthopaedic Research Society, 489, 1993.	
		Hurley et al., "Anorganic Bone – Chemistry, Anatomy, and Biological Reactions", <i>Milit. Med.</i> , 101-04, 1957.	

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		Iwasaki et al., "Bone Morphogenetic Protein-2 Stimulates Osteogenesis in High Density Culture of Periosteum-Derived Cells", Thirty Ninth Annual Meeting, Orthopaedic Research Society, 483, 1993.	
		Kershaw, "Preparation of Anorganic Bone Grafting Material", <i>Pharm. J.</i> , 8 : 537, 1963.	
		Liu et al., "Covalent Bonding of PMMA, PBMA, and Poly(HEMA) to Hydroxyapatite Particles", <i>J. Biomed. Mater. Res.</i> , 40 : 257-63, 1998.	
		Liu et al., "Polyacids as Bonding Agents in Hydroxyapatite/Polyester-Ether (Polyactive TM 30/70) Composites", <i>J. Mater. Sci.: Mater. Med.</i> , 9 : 23-30, 1998.	
		Liu et al., "Surface Modification of Hydroxyapatite to Introduce Interfacial Bonding with Polyactive TM 70/30 in a Biodegradable Composite", <i>J. Mater. Sci.: Mater. Med.</i> , 7 : 551-57, 1996.	
		Misra, "Adsorption of Zirconium Salts and Their Acids on Hydroxyapatite: Use of Salts as Coupling Agents to Dental Polymer Composites", <i>J. Dent. Res.</i> , 64 (12):1405-08, 1985.	
		Miyamoto et al., "Trans-Filter Bone Induction in Monkeys by Bone Morphogenetic Protein", Thirty Ninth Annual Meeting, Orthopaedic Research Society, 99, 1993.	
		Nishizawa et al., "Surface Modification of Calcium Phosphate Ceramics with Silane Coupling Agents", <i>Chem. Soc. Jpn.</i> 1 : 63-67, 1995. (English abstract only)	
		Pulapura et al., "Tyrosine-Derived Polycarbonates: Backbone-Modified "Pseudo"-Poly(Amino Acids) Designed for Biomedical Applications", <i>Biopolymers</i> , 32 : 411-17, 1992.	
		Reis et al., "Structure Development and Control of Injection-Molded Hydroxylapatite-Reinforced Starch/EVOH Composites", <i>Adv. Polym. Tech.</i> 16 (4): 263-77, 1997.	
		Ripamonti et al., "Growth and Morphogenetic Factors in Bone Induction: Role of Osteogenin and Related Bone Morphogenetic Proteins in Craniofacial and Peiodontal Bone Repair", <i>CRC Critical Reviews in Oral Biol. Med.</i> , 3 : 1-14, 1992.	

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		Ripamonti et al., "Initiation of Bone Regeneration in Baboons by Osteogenin, A Bone Morphogenetic Protein", <i>Matrix</i> , 12:369-80, 1992.	
		Ripamonti et al., "Induction of Bone in Composites of Osteogenin and Porous Hydroxyapatite in Baboons", <i>J. Plastic and Reconstructive Surg.</i> , 89: 731-39, 1992.	
		Ripamonti et al., "Xenogeneic Osteogenin, a Bone Morphogenetic Protein, and Demineralized Bone Matrices Including Human Induced Bone Differentiation in Athymic Rats and Baboons", <i>Matrix</i> , 11: 404-11, 1991.	
		Yasko et al., "Comparison of Recombinant Human BMP-2 Versus Cancellous Bone to Heal Segmental Bone Defects", Thirty Ninth Annual Meeting, Orthopaedic Research Society, 100, 1993.	
Examiner Signature			Date Considered

EXAMINER: Initial if reference considered, whether or not citation is in conformance with MPEP 609. Draw line through citation if not in conformance and not considered. Include copy of this form with next communication to applicant.

¹ Applicant's unique citation designation number (optional). ² Applicant is to place a check mark here if English language Translation is attached. This collection of information is required by 37 CFR 1.98. The information is required to obtain or retain a benefit by the public which is to file (and by the USPTO to process) an application. Confidentiality is governed by 35 U.S.C. 122 and 37 CFR 1.14. This collection is estimated to take 2 hours to complete, including gathering, preparing, and submitting the completed application form to the USPTO. Time will vary depending upon the individual case. Any comments on the amount of time you require to complete this form and/or suggestions for reducing this burden, should be sent to the Chief Information Officer, U.S. Patent and Trademark Office, P.O. Box 1450, Alexandria, VA 2313-1450. DO NOT SEND FEES OR COMPLETED FORMS TO THIS ADDRESS. SEND TO: Commissioner for Patents, P.O. Box 1450, Alexandria, VA 22313-1450.

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